

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)



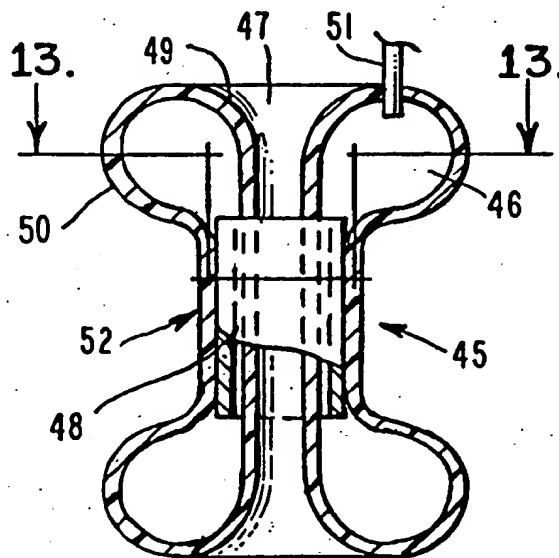
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/00		A1	(11) International Publication Number: WO 96/36283
			(43) International Publication Date: 21 November 1996 (21.11.96)
(21) International Application Number: PCT/US96/07220		(81) Designated States: CA, DE, GB, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 17 May 1996 (17.05.96)		Published With international search report.	
(30) Priority Data: 08/444,425 19 May 1995 (19.05.95) US			
(71) Applicant: GENERAL SURGICAL INNOVATIONS, INC. [US/US]; 3172A Porter Drive, Palo Alto, CA 94304 (US).			
(72) Inventors: MOLLENAUER, Kenneth, H.; 674 Hamilton Lane, Santa Clara, CA 95051 (US); MONFORT, Michelle, Y.; 11835 Skyline Boulevard, Los Gatos, CA 95050 (US).			
(74) Agents: CARLOZZI, Mark, J. et al.; Lyon & Lyon, First Interstate World Center, Suite 4700, 633 W. Fifth Street, Los Angeles, CA 90071-2066 (US).			

(54) Title: SKIN SEAL WITH INFLATABLE MEMBRANE

(57) Abstract

Surgical access devices for sealing an incision and providing a sealed access port for surgical instruments are disclosed. In one embodiment, a flexible skin seal (45) is fitted with one or more balloons (49, 50) in the inner bore (47). These balloons can be inflated after the skin seal is inserted into an incision in the abdomen. The balloons are soft and pliable and can conform to the instruments as they are moved during use. Both conventional surgical instruments and laparoscopic instruments may be inserted into the body through the balloons without disrupting the seal created by the balloons. In another embodiment, the skin seal may be provided with a balloon membrane that expands into a dumbbell, dog bone, or bow tie shaped balloon which pinches the skin between opposite ends of the dumbbell.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

DESCRIPTION**SKIN SEAL WITH INFLATABLE MEMBRANE****Technical Field**

This invention relates to the field of surgical endoscopy, specifically to
5 improvements in skin seals and cannulas.

Background of the Invention

Surgical endoscopy is a surgical technique of using small diameter long-handled tools such as graspers, forceps, scissors, retractors, dissectors, and clamps specially designed to be inserted through small incisions in the skin (or other
10 openings in the body) to perform operations within the body. The surgeon performing the surgery often cannot see the operation directly, and must watch the procedure on a video monitor which receives video image signals from an endoscopic camera or endoscope. Endoscopic surgery replaces open surgery, which requires large incisions, essentially opening the body cavity completely, in order to
15 perform surgery deep within the body. Endoscopic techniques have been used for gall stone removal, gall bladder removal, hernia repair, tumor removal, lymph node removal and appendectomy and many other operations. Endoscopic surgery is also called laparoscopic surgery, video assisted surgery, minimally invasive surgery, and band-aid surgery, but throughout this specification the term endoscopic surgery or
20 laparoscopic surgery will be used.

To illustrate the background of the inventions described below, the example of the laparoscopic cholecystectomy, hernia repair or lymphadenectomy, as well as the operation for harvesting a blood vessel, will be used to illustrate both the old laparoscopic procedures and the new laparoscopic procedures now possible with the
25 new devices. In the old procedure, a working space was created in the abdomen using the process called pneumoperitoneum or insufflation. Insufflation is the process of injecting gas into the body to blow it up like a balloon, creating a space filled with gas. When performed on the abdomen, the peritoneum is insufflated and

the procedure is known as pneumoperitoneum. The procedure can be used for insufflating a space between the peritoneum and the skin to permit laparoscopic hernia repair, as illustrated in U.S. Patent No. 5,496,345 to Kieturakis et al., entitled, "An Expansible Tunneling Apparatus for Creating an Anatomic Working Space." Insufflation can also be used to inflate a tunnel shaped working space over a blood vessel to facilitate blood vessel harvesting, as described in commonly assigned U.S. Patent Application Serial No. 08/267,484, entitled "Extraluminal Balloon Dissection Apparatus and Method," the disclosure of which is hereby incorporated by reference in its entirety. While the space is filled with gas, the surgeon inserts long slender laparoscopic tools through trocars and cannulas which pierce the skin and provide access ports into the insufflated space.

For abdominal surgery such as a cholecystectomy (gall bladder removal), the insufflation is accomplished by the following procedure. An incision is made at the lower edge of the belly button or umbilicus. The surgeon uses his fingers or a blunt dissection tool such as a blunt nosed obturator to uncover the fascia or abdominal muscles, then a large needle referred to as a Verres needle is inserted into the abdomen or peritoneal cavity. The Verres needle punctures the fascia and peritoneum which cover the abdomen. A pressurized gas such as CO₂ is injected into the abdomen through the needle, in effect inflating the abdomen like a balloon. After the abdomen is insufflated, the Verres needle is removed. After the needle is removed, trocars and cannulas are inserted into the space created by the insufflation. Endoscopic instruments including an endoscope or laparoscope, scissors, graspers, etc., are inserted into the abdomen through the cannulas and manipulated to dissect tissue surrounding the gall bladder, remove the gall bladder, and stitch the internal wounds.

To harvest the saphenous vein using laparoscopic procedures, the surgeon may insufflate a tunnel shaped work space created over a blood vessel. The tunnel is first created using obturators or tunneling devices or balloons inserted through small incisions along or over the saphenous vein. After the tunnel is created, the surgeon may insert skin seals and cannulas, and insufflation gas is injected through one of the trocars. While the tunnel is insufflated, the cannulas permit the surgeon

to insert laparoscopic instruments into the tunnel to perform surgery on the saphenous vein.

The cannula used in the procedures described above is a length of rigid tube. The trocars and cannula are designed to allow laparoscopic instruments to pass through them and prevent gas from escaping the abdomen or other insufflated work space. The cannula may have a flapper valve or a trumpet valve inside which opens to allow an endoscope or laparoscope or other instrument to pass through, and closes when the laparoscope is removed. Some trocar/cannula devices also contain a duckbill valve to assist in sealing the trocar. The cannulas are typically about 6 inches or 15 centimeters long, and come in diameters matching various laparoscopic devices, generally from 2 to 15 mm.

Some surgeons use bare cannulas, secured only by a tight fit with the skin and fascia. However, cannulas frequently slip out of the body during use, disrupting the procedure and possibly endangering the patient. To prevent this danger, surgeons have devised a variety of methods to secure the cannula to the body and prevent it from slipping out of the body. Some cannulas are provided with threaded sleeves, fixed to the cannula. Some cannulas are provided with a threaded gripper with a smooth inner bore which matches the size of the cannula, so that the cannula can slide inside the gripper as shown in Fig. 2. The gripper stabilizes the cannula so that it will not slip out of the body inadvertently, but can be easily removed when the surgeon wants. The threaded gripper is simply screwed into the incision in the skin. This option permits the ready insertion and removal of smooth walled cannulas by sliding them into and out of the gripper. Other grippers have been used, such as a gripper with expandable arms, a gripper with an inflatable balloon on the outside, and the Hasson cannula. These devices are illustrated in Oshinsky, et al., Laparoscopic Entry and Exit, reprinted in Urologic Laparoscopy at 91-101 (Das & Crawford ed. 1994). These devices are variously referred to as threaded skin seals, screw skin seals, skin anchors, obturators, grippers, trocar stabilizers or cannula stabilizers.

The surgeon usually needs to place several trocars and cannulas into the abdomen, and inserts as many as needed to accomplish the intended operation. The first cannula placed through the belly button is used to insert a laparoscope so that

the placement of other trocars and cannulas can be viewed from inside the abdomen. After several cannulas are in place, the surgeon can view the procedure through any port, and can insert laparoscopic scissors, cutters and graspers and other tools through the cannulas in order to perform the surgery. The typical endoscopic graspers 3 used for stitching inside the abdomen are shown, deployed inside the cannulas, in Fig. 2. A bare cannula 4 is used with endoscopic graspers 3a. Another pair of laparoscopic graspers 3b is inserted into a cannula 4a which is inserted through a threaded gripper 5. A third cannula 6, shown with a threaded outer surface, is provided for an endoscope 34 which is inserted into the work space to provide the surgeon with a video view of the graspers 3 and body tissue.

The small diameter of the cannulas keeps the incisions small, and the matching diameter of the laparoscopic instruments is necessary to prevent leakage of the insufflation gas from the abdomen. Laparoscopic instruments of various designs are available, and they generally are about 5 to 12 mm in diameter (to match the inside bore of the cannulas) and about 10 to 40 cm in length. They are long and therefore difficult to use, and they are usually used when the surgeon can see them only through the laparoscope. Modern laparoscopic procedures require the surgeon to view the procedure on a video monitor. It may take a surgeon a lot of practice before becoming comfortable and skillful with the laparoscopic graspers, grippers and scissors. These tools are more difficult to use than the surgical tools which every surgeon uses in normal surgery, such as those shown in Fig. 3, in use during open laparotomy. The normal graspers are shown in use while the surgeon is tying off a suture 9. This normal procedure is familiar to a large number of surgeons. The normal surgical graspers 7a and 7b are shown in use in Fig. 3, suturing body tissue 8 with suture 9. It can readily be appreciated that the laparoscopic graspers shown in Fig. 2 require significantly more skill than normal surgical tools. One of the drawbacks of known cannulas and grippers is that they are adapted to admit only relatively narrow instruments, and are therefore generally unsuited for use with surgical tools designed for open procedures.

It would be advantageous to use conventional surgical tools during laparoscopic procedures, but this is usually not permitted by the typical construction of the trocars and cannulas which are too narrow, long and rigid to permit passage

of the conventional surgical tools. Most surgeons are very well trained in using conventional non-endoscopic instruments, such as the open-incision graspers shown in Fig. 3, and numerous procedures involving the graspers such as tying off a suture are well known and well practiced. The endoscopic instruments shown in Fig. 2, on the other hand, are not well known and well practiced, and generally require significantly more skill than the more familiar conventional open-incision instruments. Thus, there is a need to provide cannulas and grippers which would accommodate instruments used in open incision procedures.

Disclosure of the Invention

10 In a typical endoscopic or laparoscopic operation, a surgeon creates a working space inside the body through insufflation. To create the working space for abdominal surgery, the surgeon makes a small incision at, for example, the inferior margin of the umbilicus 1 as shown in Fig. 1, and then uses his fingers or a dissecting tool such as a blunt nosed obturator to prepare a point of injection. The
15 surgeon then inserts a Verres needle 2 into the abdominal cavity, and causes a pressurized gas such as CO₂ to flow through the needle 2 and into the abdominal cavity. This inflates the abdomen as shown in Fig. 1 and provides a working space for the surgeon. The needle may then be removed, and a cannula or trocar/cannula combination may be inserted into the incision. Additional incisions may also be
20 made, and the first incision may be used to insert a laparoscope to assist in the placement of the other incisions. The additional incisions may each receive a cannula, and once several cannulas are in place the surgeon can view the procedure, and/or insert laparoscopic scissors, cutters, graspers or other tools through any of the cannulas.

25 As mentioned above, the trocars and cannulas can be used in endoscopic blood vessel surgery, laparoscopic cholecystectomy and laparoscopic hernia repairs where a working space is created under the skin. In the blood vessel harvesting operation where the saphenous vein is to be removed, a surgeon creates a tunnel between two small incisions over the saphenous vein. Then a cannula and skin seal
30 are inserted into each incision. The tunnel is insufflated through one of the cannulas. In these procedures, the laparoscopic instruments are also inserted into

the working space through the cannulas, and the surgeon can watch the surgery through a laparoscope inserted through the one of the cannulas.

The devices presented herein allow for use of normal surgical tools (such as the forceps and scissors used in open-incision surgery) in laparoscopic procedures.

- 5 The skin seal is fitted with one or more balloons on the inner bore. These balloons can be inflated after the skin seal is inserted into the incision in the abdomen. Placement of the skin seal can be accomplished as usual, with the aid of a blunt or sharp trocar or cannula placed within the threaded skin seal. The threaded skin seal can be made of rigid plastic, as is customary, or preferably it may be made of soft and pliable material such as latex or silicone rubber. When the threaded skin seal is in place, the trocar may be removed and the balloon may be inflated until it expands to fill the inner bore of the threaded skin seal, thus sealing the bore to maintain the pressure created inside the abdomen with the insufflation gas. The balloons are soft and pliable and can conform around the elements of the instruments as they are moved about during use. Thus, normal or conventional surgical instruments may be passed between the balloons. Both normal surgical instruments and laparoscopic instruments may be inserted into the body through the balloons without disrupting the seal created by the balloons. The balloon is soft and pliable so that normal surgical tools may be operated inside the inflated balloon segments and the balloon segments will not hamper the operation of the tool to a significant degree. The skin seal may be provided with a balloon membrane that expands outside the lumen of the skin seal to create a dumbbell, dog bone or bow tie shaped balloon which pinches the skin and, when necessary, fills the lumen in the skin seal.
- 10
15
20

- More than one tool may be inserted through a single skin seal because the balloons are sufficiently pliable and may be inflated to a lesser degree. In this manner, normal surgical instruments may be used in laparoscopic procedures, taking advantage of the fact that they are easier to use and more surgeons know how to use them, compared to the long laparoscopic instruments. The balloon filled skin seal may be used also as a seal for laparoscopic incisions which are no longer necessary or which the surgeon desires to plug temporarily while still leaving a skin seal in place for later use.
- 25
30

Brief Description of Drawings

Fig. 1 is an external view of the insufflated abdomen of a patient.

Fig. 2 is a cross-section of the insufflated abdomen of a patient with several trocars, cannulas and laparoscopic instruments in place for a laparoscopic procedure.

5 Fig. 3 is a view of an open laparotomy procedure using normal surgical forceps.

Fig. 4 is an exploded view of cannula with an inflatable balloon inside.

Fig. 5 is a cross-sectional view of the cannula with the inflatable balloon inside.

10 Figs. 6, 6a and 6b are cross-sectional views of the cannula with the inflatable balloon shown in its inflated state.

Figs. 7 through 7c are end views, from the proximal end, of the cannula with inflatable balloon inside.

15 Figs. 8 shows a pair of skin seals with the balloons inside with a normal surgical instrument inserted through the balloons, deployed in the manner of intended use.

Fig. 9 shows a blunt obturator suited for use with the skin seal.

Fig. 10 shows a sharp trocar type obturator or suitable for use with the skin seal.

20 Fig. 11 shows the blunt obturator inserted in the skin seal.

Fig. 12 shows a skin seal with balloons which expand outside the lumen of the skin seal.

Fig. 13 is a cross-section of the skin seal with outer balloon.

25 Fig. 14 shows an alternate embodiment of a skin seal with balloons which expand outside the lumen of the skin seal.

Fig. 15 shows an exploded view of the skin seal with butterfly-shaped balloon membranes.

Fig. 16 shows the skin seal with outer balloon prepared for insertion into an incision.

30 Figs. 17 through 17b show a skin seal with outer balloon inserted into an incision.

Fig. 18 shows an alternate embodiment of the skin seal.

Best Mode for Carrying Out the Invention

The cannulas and grippers described below allow for use of normal surgical instruments in laparoscopic surgical procedures. In the context of this invention, the terms "cannula," "skin seal," and "gripper" are used substantially interchangeably. The typical gripper configuration is modified by adding a balloon or inflatable membrane to the inner bore of the gripper and adding an inflation port to the wall of the gripper to allow for inflation of the balloon. When the balloon is inflated, it closes off the inner bore of the gripper so that it provides an air-tight seal during insufflation. The balloon is pliable so that tools can be inserted through the inner bore of the balloon and the balloon expands around the surgical tool to maintain the seal with little or no leakage of insufflation gas.

Referring to Fig. 4, the threaded skin seal 10 has a tube 11 with a generally conical or frustum outer shape with screw threads 12 provided on the outer surface 13. The inner bore 14 is conical or funnel-shaped, conforming generally to the outer shape. Overall, the skin seal is funnel-shaped, and the proximal end 15 of the threaded skin seal 10 has a large opening, and the distal or bottom end 16 has a smaller opening. The distal or bottom portion 16 of the threaded skin seal 10 may have a straight or cylindrical bore to provide a tight fit with cannulas that have an outer diameter matching the inner diameter of this straight bore. The distal or bottom portion 16 of the skin seal 10 may have a straight or cylindrical outer shape to make it easier to screw the skin seal 10 into an incision, and this straight section may be made of variable length to match the different thickness of fat which will be encountered in different patients. The proximal end preferably has a conical inner bore to facilitate insertion of tools into the opening and through the cannula, but the inner bore may be straight. The proximal end may also be described as flared, and may be gradually flared in relation to the distal end, as though trumpet shaped, or may flared in discrete fashion as in a typical funnel, with a straight tube at distal end and a conical segment at the proximal end. The screw threads 12 constitute a fastening means, and may be replaced with other fastening means such as a circumferentially ribbed outer contour or a longitudinally grooved outer contour. As shown, a flange 19 may be provided on the proximal end of the skin seal 10 for ease of handling. The flange 19 also provides a convenient means for

mounting the bellows onto the skin seal 10. The skin seal is preferably 1 to 3 inches, or about 2 to 8 centimeters, long.

A balloon membrane 20 has a generally conical or frustum shape matching the inner bore of the threaded skin seal 10 and having the same overall length as the threaded skin seal 10. The balloon membrane 20 fits inside the threaded skin seal 10 and is sealed to the skin seal funnel at the upper edge and lower edge of the balloon membrane. The balloon membrane 20 may be shorter than the skin seal 10, and may be sealed to the inner surface of the skin seal 10 at points inside the skin seal 10, rather than at the immediate distal and proximal edges of the skin seal 10. Also, the balloon membrane 20 may be longer than the skin seal 10 and may be cuffed or folded back around the outside of the skin seal 10 at the proximal and distal ends, and sealed at the cuffs.

An inflation port 21 is provided comprising a hole in the wall 22 of the threaded skin seal 10. An inflation tube 23 or Luer fitting connects the inflation port 21 to a suitable pump such as the syringe 24 shown in Fig. 5 or to the squeeze bulb 25 shown in Fig. 6. When the syringe 24 is used, the membrane 20 may be inflated and deflated repeatedly by pushing and pulling on the syringe plunger 26, thus forcing air into the balloon membrane 20 and sucking air out of the balloon membrane 20. A one-way valve or stopcock may be used to seal the membrane 20 so that the pump or syringe may be detached from the skin seal 10. Alternately, an inflation port can be provided at the distal tip of the skin seal, comprising an open airway between the inflatable membrane 20 and the insufflated work space. In this manner, the insufflation gas enters the skin seal from inside the body to pressurize and inflate the inflatable membrane. In this manner, an automatic seal is created upon insertion of the skin seal into the insufflated space. This simplifies placement and use of the skin seal because there is no need for a separate syringe or pump to inflate the membrane.

In the preferred embodiment, the bladder 20 is made of biocompatible elastomeric or elastic material such as latex, silicone rubber or any other suitable compliant or inflatable material. The skin seal 10 is made of rigid or flexible material, soft or hard plastic, high density or low density polyethylene,

polypropylene, thick latex, silicone rubber or any other suitable material including plastic, elastic or nonelastic biocompatible material.

As shown in Figs. 4 and 5, the inflatable skin seal may be constructed by applying an elastic cylindrical or conical balloon membrane 20 to the inner bore of skin seal 10 and sealing the distal end of the balloon 20 to the distal end of the skin seal and sealing the proximal end of the balloon to the proximal end of the skin seal, thereby creating an inflatable space between the skin seal cannula 10 and the membrane 20. Alternatively, a fully formed balloon bladder, comprising inner and outer conical membranes sealed to each other at their distal and proximal ends, can be provided and fixed to the inner bore of the cannula. The overall shape of the balloon will be conical, funnel shaped or flared to match the shape of the inside of the skin seal 10. While one balloon is depicted in each of the Figs., two or more balloons may be used to guard against the possibility of rupture and loss of insufflation pressure during an operation, or to facilitate manufacture, or to facilitate use of the skin seal with particular tools. A membrane seal may be provided at any cross-sectional plane within the skin seal 10 to guard against loss of insufflation pressure.

Fig. 6 shows the inflatable skin seal 10 with the membrane 20 in its inflated condition. The squeeze bulb 25 is used to force air into the space between the bladder 20 and the wall of the skin seal 10, causing the membrane 20 to inflate within the skin seal 10. The inflated membrane 20 can be inflated until it completely obstructs the inner bore of the skin seal 10 and provides an air-tight seal between the distal and proximal ends of the skin seal 10. The skin seal or cannula 10 can be thin walled and flexible enough to expand as well, thereby further improving the seal between the skin seal 10 and the incision. As shown in Fig. 6a, the membrane 20 need not extend for the full length of the skin seal 10, but may instead be sealed to the inner bore at various points inside the skin seal 10. The skin seal 10 in Fig. 6a has a balloon 20 only in the conical inner bore of the proximal section of the skin seal 10, and this facilitates use of graspers, scissors and other such instruments which might pinch the balloon 20 when operated, or unnecessarily reduce the internal diameter of the narrowest portion of the cannula. As shown in Fig. 6b, the wall of the skin seal 10 may be made flexible enough to

expand outwardly when the skin seal 10 is inflated, so that any gaps or looseness in the seal between the outside of the skin seal 10 and the incision are closed by the expansion of the outer wall 22 of the skin seal 10.

Fig. 7 shows the view of the inflated membrane viewed from the proximal end of the skin seal 10. The membrane naturally bulges in two or more radial sections or segments 27 to fill the lumen of the skin seal 10. The expansion of the balloon sections 27 need not be controlled, but may be controlled to facilitate operation of graspers or other hinged and pinching tools. For example, the application of restrictors, comprised of thickened strips along the length of the membrane, shown in Fig. 7a, may be applied to the membrane to inhibit expansion along the strip. Wire bands, plastic bands, or a line of adhesive gluing the balloon membrane to the skin seal may also be used to prevent expansion of the membrane along a longitudinal line of the membrane extending from the proximal end (or near the proximal end) to the distal end (or near the distal end) of the funnel. In this manner, a uniform expansion can be obtained, with the membrane expanding from the walls of skin seal 10 to meet along a uniform plane. A pinching tool used in the skin seal 10 can be opened and closed along the plane defined by the inflated balloon, and the balloon will pliantly close upon the lumen but allow the pinching tool to open and close with less chance of pinching and cutting the balloon. As shown in Fig. 7b, the inflatable membrane 20 may be placed on the inner bore of the skin seal in an eccentric manner, covering only a portion of the inner wall of the skin seal. Fig. 7c shows the eccentric inflatable membrane in its inflated state.

Fig. 8 shows the skin seals 28, 29 and 30 with the balloon membranes inflated. Skin seal 28 has the funnel shape described above. A pair of normal surgical scissors such as Metzenbaum scissors 31 is inserted through one skin seal 28 and a pair of normal surgical graspers 7 (examples include Kelly clamps, Kelly placenta forceps, and Mayo clamps) is inserted through the skin seal cannula 29 to perform operations beyond the distal tip of the cannula. The skin seals are shown screwed into incisions through skin 32 and subcutaneous fat 33, and they may also extend through the peritoneum or other tissue when appropriate to the operation. An endoscope or laparoscope 34 which can be inserted through one skin seal to provide a view of the procedure is shown in the central skin seal 30. Because the

balloon is pliable and conforms around any device within the skin seal, the graspers 7 may be manipulated inside the cannula without breaking the insufflation seal. As the graspers 7 are manipulated, the membrane conforms around graspers 7 but yields to allow the graspers 7 to be opened, closed, twisted, pushed, and pulled within the skin seal without substantially degrading the seal created by the membrane. It should be noted that a perfectly air-tight seal is not necessary, and some leakage of insufflation gas or fluid is acceptable, so long as insufflation gas or fluid can be injected at a rate sufficient to make up for any losses. Where the skin seal itself is made of a soft pliant material such as latex rubber or silicone rubber, the forceps may be manipulated even further, and deformation of the skin seal 28 will permit a wider range of motion for the forceps. Skin seal 28 is shown with a pair of conventional surgical scissors 33 or shears disposed through the skin seal. The scissors may be opened wide, as shown, and the distal or proximal end of the skin seal will yield and flare out to allow operation of the scissors through their full range of motion and opened through the full throw (the "throw" referring to the length of arc 35 over which the graspers or scissors may be opened) of scissors 33 or graspers, as illustrated by flared distal portion 36 of skin seal 28.

It will be readily appreciated that such operation would not be possible using standard cannulas. Normal surgical tools are much easier to use than the long laparoscopic instruments shown in Fig. 2. Also, the tools can be much larger, and have much larger operating implements. For example, the cutting edges of scissors 31 are much longer than cutting edges on laparoscopic scissors, and can cut much more quickly. A common method of dissecting tissue with conventional scissors is to pierce connective tissue with the closed scissors and open the scissors, operating the scissors in backwards fashion, so that the dull outer edges of the scissors pull connective tissue apart. This can be done very quickly using the skin seals 29 and 30, as compared to slow and tedious snipping required when using long laparoscopic instruments.

Placement of the skin seals may be facilitated with the special blunt obturators shown in Figs. 9, 10 and 11. The blunt obturator 37 provides support for the skin seal as it is pushed and screwed into the incision. The blunt obturator comprises a peg 38 with an outer contour which matches the inner bore of the skin

seal, a handle 39 a finger gap 40, and a blunt tip 41. The tip may be blunt and rounded, or it may be sharp and pointed, as illustrated by the sharp pointed trocar type tip 42 in Fig. 10, in which case the sharp point 42 can puncture body tissue. The obturator is placed inside the skin seal as shown in Fig. 11, and the assembly
5 is screwed into the body as a unit. After the skin seal is in place, the obturator is removed to allow insertion of other devices into the skin seal. The finger gap 40 leaves some space for the surgeon to push against the flange of the skin seal while pulling the handle 39, thus avoiding the possibility that the skin seal will be pulled out of the body with the obturator 37. Because the obturator 37 fits tightly inside
10 the skin seal to give it support during insertion, it may inadvertently become sealed to the inside of the skin seal, especially if there is any leakage of body fluids or water into the skin seal. Any excessive force required to pull out the obturator could result in pulling the screw skin seal out of the skin incision. To prevent the need for such excessive force, the portion of the obturator which fits inside the skin
15 seal may be provided with vacuum breakers in the form of scored lines or channels 43, circumferential grooves 44, or a roughened surface, to prevent a vacuum from forming between the skin seal inflatable membrane. The scoring or roughening may take any form.

Fig. 12 shows another embodiment of the skin seal in which the balloon is
20 enlarged so that it expands outside the lumen of the skin seal. The skin seal 45 shown in Fig. 12 includes a dumbbell shaped balloon 46. The shape of the balloon may variously be described dog bone, bow tie, dumbbell or butterfly shaped. The balloon 46 has a lumen 47 extending through the balloon, and can be provided with a rigid cannula segment or stiffener tube 48 disposed within the balloon 46. The
25 stiffener tube 48 need only be stiff enough to provide support for the balloon 46 during placement, so it is stiff in relation to the balloon membrane, but may in fact be very flexible, and can be made of any plastic or elastic material or other materials suitable for the balloon membrane.

The balloon 46 may be formed by sealing together an inner balloon tube 49
30 and an outer balloon membrane 50. An inflation port 51 is provided on the outer dumbbell portion, but may also be provided on the middle portion 52 or even the inner dumbbell. If inflated by insufflation, an inflation port may be provided on the

inner dumbbell in form of a simple airway provided in the inner dumbbell which allows insufflation gas to enter the balloon 46 from the insufflated space. In this manner, the need for a separate source of inflation gas or fluid is avoided.

The outer balloon membrane 50 may be made of two or more pieces to
5 create any desired outer shape. As shown in Fig. 13, the outer balloon membrane 50 has an oval outer shape when inflated. The balloon may be provided with any other useful shape, and may be round or toroidal, or oval as shown. The balloon is formed of two pieces 53 and 54 which are heat sealed or sealed with adhesive along the seam 55. Fig. 13 also illustrates that the inner balloon tube 49 fits inside
10 the lumen of the stiffener tube 48 while the outer balloon membrane 50 surrounds the stiffener tube 48. Fig. 15 shows an exploded view of the device, with butterfly shaped balloon membranes 53 and 54, the inner balloon tube 49 extending across the "wingspan" or major length of the butterfly shaped membrane, and the stiffener tube 48 surrounding the tubular balloon membrane 49. With the inner balloon tube
15 49 and the stiffener tube 48 sandwiched between the butterfly shaped balloon membranes, the edges of the butterfly shaped membranes are sealed together and the ends of the inner balloon tube 49 are sealed to the edge of the butterfly shaped membranes at the middle of the outer edge of the wings, thereby forming a single balloon with an overall butterfly shape and a lumen extending across the wingspan.
20 The balloon can be made of any suitable material, including polyethylenes, polyamide, polyurethanes, latex or silicone rubber. The balloon may be elastic or non-elastic. The various pieces may be made of different material, for example the inner balloon tube may be made of an elastic material and the outer balloon membranes may be made of non-elastic material.

25 The stiffener tube 48 may be a straight length of tube or it may be funnel shaped like the screw skin seals described above. The stiffener tube 48 provides columnar support for the device so that it can be pushed through an incision in the skin. The stiffener tube 48 may be made of any suitable material, including any material previously mentioned above and any material previously used for cannulas
30 and trocars. The length of the stiffener tube is chosen to approximate the thickness of the skin and fat layers, and is preferably slightly shorter than the thickness of the skin and fat layers. The stiffener tube 48 may be disposed inside the balloon pieces

without being sealed in any way to the balloon pieces, or it may be sealed to either the inner or outer balloon pieces.

The inner balloon tube 49 may be sealed along a circumference of the tube, just as the balloon membrane of Figs. 5 and 6 is sealed to the threaded skin seal, and it may be sealed to the stiffener tube along one or more longitudinal lines as shown in Fig. 7a. The inner balloon tube 49 may also be provided with thickened longitudinal portions, metal or plastic bands, etc., as described with reference to Fig. 7a to control inflation and encourage inflation toward a uniform plane in the center of the lumen. Also, the inner balloon tube 49 may be sealed to the stiffener tube 48 at both ends of the stiffener tube 48, as is the balloon membrane of the threaded skin seal, and inflated through an optional airway 56. The outer balloon pieces may be sealed to the outside of the stiffener tube 48, either by sealing the entire intermediate portion to the stiffener tube 48 or by dispensing with the intermediate portion and sealing the dumbbell portion of the balloons to the ends 57- and 58 of the stiffener tube 48, as shown in Fig. 14.

In use, the distal end of the deflated balloon is tucked into or pulled into the stiffener tube 48, as shown in Fig. 16. An obturator, trocar or cannula 59 is placed inside the stiffener tube 48 to facilitate insertion of the skin seal 45 into an incision. The cannula 59 is pushed into the incision along with the skin seal 45 which rides over the cannula 59. With the cannula 59 in the incision, the skin seal 45 can be pushed over the cannula 59 and into the incision. After the skin seal 45 has been inserted into the incision, the cannula 59 may be removed leaving the skin seal 45 in place. Then the balloon can be inflated, as shown in Fig. 17. When the balloon is inflated, the outer dumbbell portion 60 is inflated while the inner dumbbell portion 61 expands out of the stiffener tube 48 into the body and inflates to re-establish the dumbbell shape. When the balloon is inflated further, the expanding dumbbells clamp down on skin 32, fat 33 and other tissue is trapped between the inner dumbbell portion 61 and outer dumbbell portions 60. When the balloon is inflated, the inner balloon tube 49 tends to collapse and fill the lumen 47 or tends to seal any device, such as the endoscope 34 placed through the lumen, as shown in Fig. 17. A trocar or cannula may be inserted into the body through the lumen 47 of the skin seal, to allow insertion of laparoscopic instruments through the

cannula, or laparoscopic instruments and normal surgical instruments may be inserted through the skin seal as shown in Fig. 17a and 17b, where the inner balloon tube 49 conforms around the instruments. Fig. 17a shows the same skin seal with a pair of normal graspers used for open surgery inserted into the body through the skin seal. Fig. 17b shows the skin seal inflated so that the inner balloon tube 49 completely fills the lumen 47 of the skin seal, thus maintaining the insufflation of the working space below the skin seal.

In another embodiment, only the inside or distal end of the balloon expands outside the skin seal. As shown in Fig. 18, the stiffener tube is provided with a flange 62 on the proximal end. The inner balloon tube is sealed to the inside of the stiffener tube at the proximal end of the tube. The outer balloon portion is sealed to the outside surface of the stiffener tube. The inner or distal dumbbell portion is expanded inside the body, and inflation of the distal dumbbell portion clamps the skin and fat between the flange and the distal balloon. When the central lumen is not occupied by an instrument, the inner balloon tube is collapsed into the central lumen by the pressure in the balloon and establishes a seal between the insufflated work space and the outside. The seal can be supplied in a variety of sizes, with stiffener tubes of various sizes to match commercially available trocars, cannulas and laparoscopic instruments. The size of the balloon and the length of the stiffener tube can be varied to fit incisions of various sizes required by the many different operations with which the skin seal can be used. The skin seal may be used for laparoscopic access in any procedure, and can also be used to compress bleeding incisions and plug unneeded incisions during laparoscopic surgery.

The skin seals described above can be used for any endoscopic or laparoscopic surgery to permit use of conventional surgical instruments i.e., ordinary open incision surgical instruments. While the skin seals described above are useful in procedures requiring insufflation, they may also be used in other endoscopic or laparoscopic procedures. The use of the skin seal in any endoscopic or laparoscopic procedures will allow deployment of conventional surgical tools while protecting the area of the incision from trauma caused by the operation of the surgical instruments. Where insufflation or flushing is required, the bladder in the skin seal may be inflated to prevent undesired flow out of the cannula. Also,

although the skin seal described above has been described in the best known embodiments, fabricated with suitable materials known to the inventors, the particular materials and shapes depicted in the illustrations may be altered and improved upon without departing from the inventions as claimed. It is specifically
5 contemplated that the materials be improved upon. Furthermore, although the devices have been described in relationship to surgery requiring insufflation and endoscopic or laparoscopic surgery, the claimed devices and methods may be used in surgical and non-surgical applications wherever the features of these device and methods prove beneficial.

What is Claimed is:

1. A device for sealing an incision through one or more layers of body tissue and providing access for surgical instruments to be passed into the body comprising:

5 a balloon having a distal portion, a proximal portion, an intermediate portion between said distal and proximal portions, said distal portion having a large cross-section compared to said intermediate portion, said balloon having an inner balloon tube and an outer balloon tube defining a lumen which extends through said balloon and through which the surgical instruments can be passed into the body, said
10 inner balloon tube and said outer balloon tube being sealed together at said distal and proximal portions of said balloon to form a closed surface which can be inflated;

a tube having proximal and distal ends disposed within said closed surface of said balloon, said inner balloon tube extending through said tube and said
15 outer balloon tube surrounding said tube, said tube having a length approximately equal to a thickness of the layers of body tissue to be sealed and a lumen extending therethrough; and

an inflation port communicating with said closed surface of said balloon.

20 2. The device of claim 1 wherein said outer balloon tube is comprised of two butterfly shaped balloon membranes having outer margins, said butterfly shaped balloon membranes being sealed to each other along their outer margins to form a butterfly shaped balloon.

3. The device of claim 1 wherein said distal portion of said balloon has
25 a large diameter compared to said intermediate portion of said balloon, said diameter being sufficient to ensure that said distal portion of said balloon, when inflated, is large enough to cover the incision.

4. The device of claim 1 further comprising a flange on said proximal end of said tube, said flange being sized and dimensioned to cover the incision.

5. The device of claim 1 wherein said distal portion of said balloon is stored within said lumen of said tube when said balloon is uninflated, said distal portion of said balloon everting and expanding outside said lumen upon inflation.

6. A surgical access device comprising:
a flexible funnel having a large end, a small end, an outer surface, and an inner bore;

screw threads on said outer surface of said funnel;
10 a funnel shaped inflatable membrane secured to said inner bore of said funnel to form an airtight chamber between said inner bore of said funnel and said inflatable membrane; and

an inflation port communicating with said airtight chamber.

7. A skin seal comprising:
15 a flexible tube having a proximal end, a distal end, and an inner bore, said proximal end having a larger outer diameter than said distal end;

an inflatable membrane secured to said inner bore of said flexible tube, said inflatable membrane having a proximal end of larger diameter than said distal end, said inflatable membrane being disposed within said tube with said
20 proximal end of said inflatable membrane aligned with said proximal end of said tube and said distal end of said inflatable membrane aligned with said distal end of said tube, said inflatable membrane sealed to said tube; and

an inflation port communicating with said inflatable membrane.

8. A surgical access device comprising:
25 a flexible tube having a proximal end and a distal end, said proximal end having a larger diameter than said distal end, said tube having an outer surface and an inner bore;

an inflatable membrane disposed within said inner bore of said flexible tube, said inflatable membrane having a conical shape and having a proximal end and a distal end, said inflatable membrane sealed to said tube; and an inflation port communicating with said inflatable membrane.

5 9. The device of claim 8 further comprising screw threads on said outer surface of said flexible tube.

10 10. The device of claim 8 further comprising a flange on said proximal end of said flexible tube.

 11. The device of claim 8 wherein said flexible tube is made of an
10 elastomeric material.

 12. The device of claim 8 wherein said flexible tube is made of a nonelastic material.

 13. The device of claim 8 wherein said inflatable membrane is disposed only within said proximal end of said flexible tube.

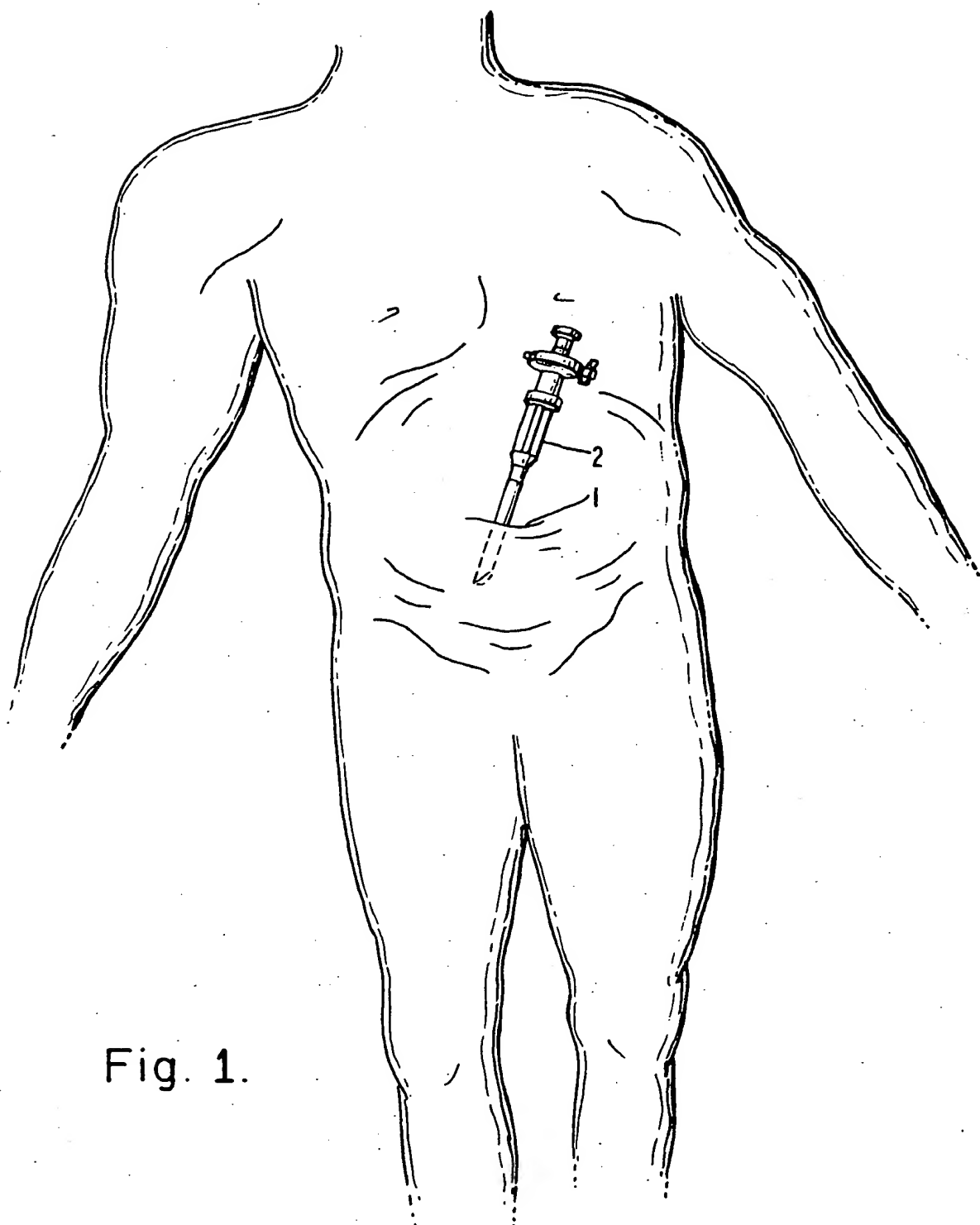


Fig. 1.

SUBSTITUTE SHEET (RULE 26)

Fig. 2.

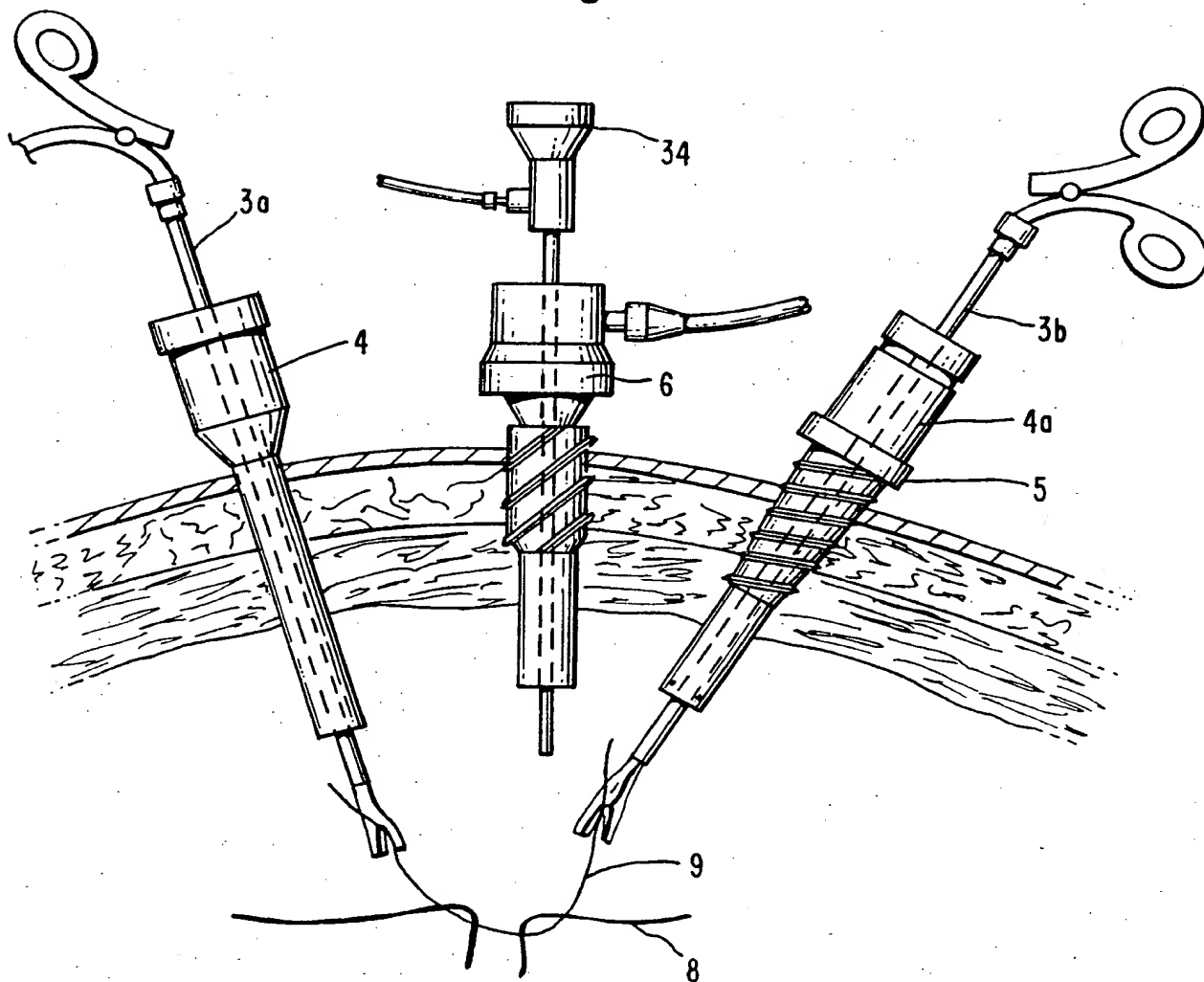
**SUBSTITUTE SHEET (RULE 26)**

Fig. 3.

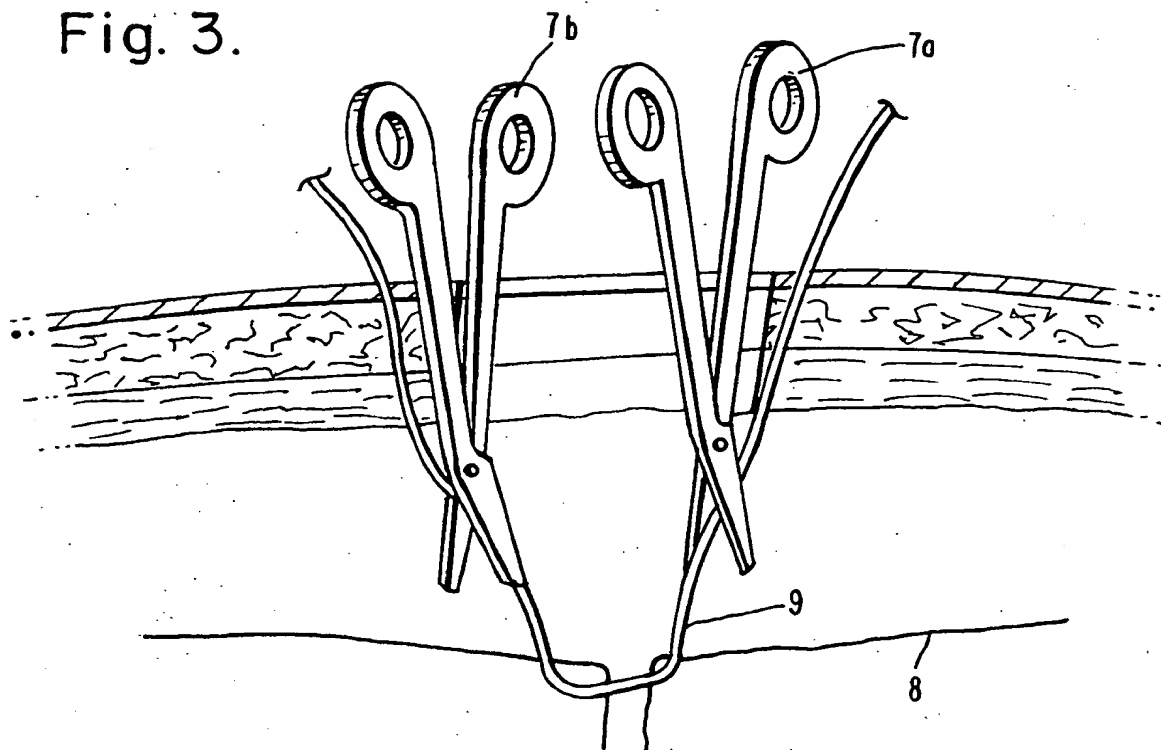


Fig. 4.

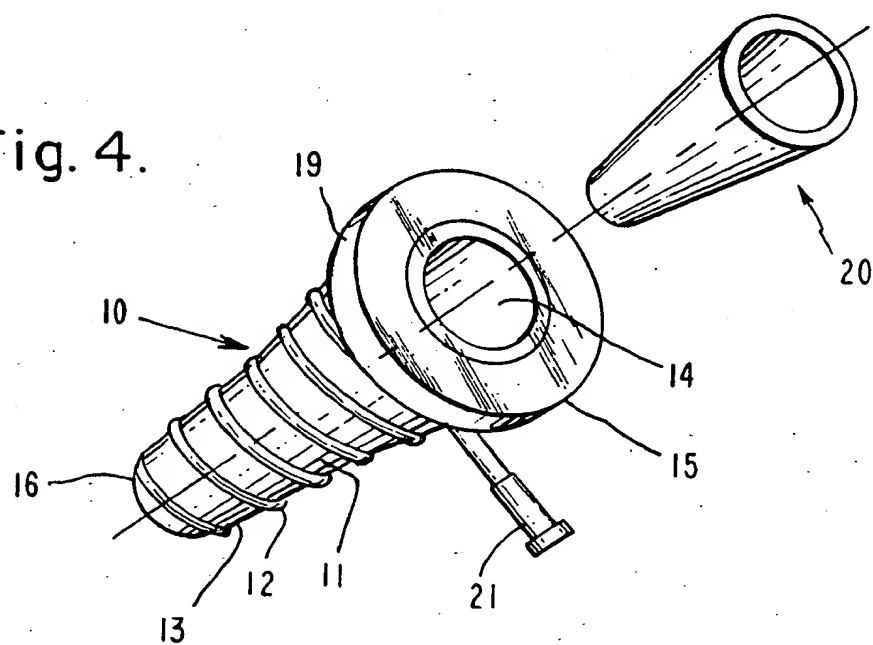
**SUBSTITUTE SHEET (RULE 26)**

Fig. 5.

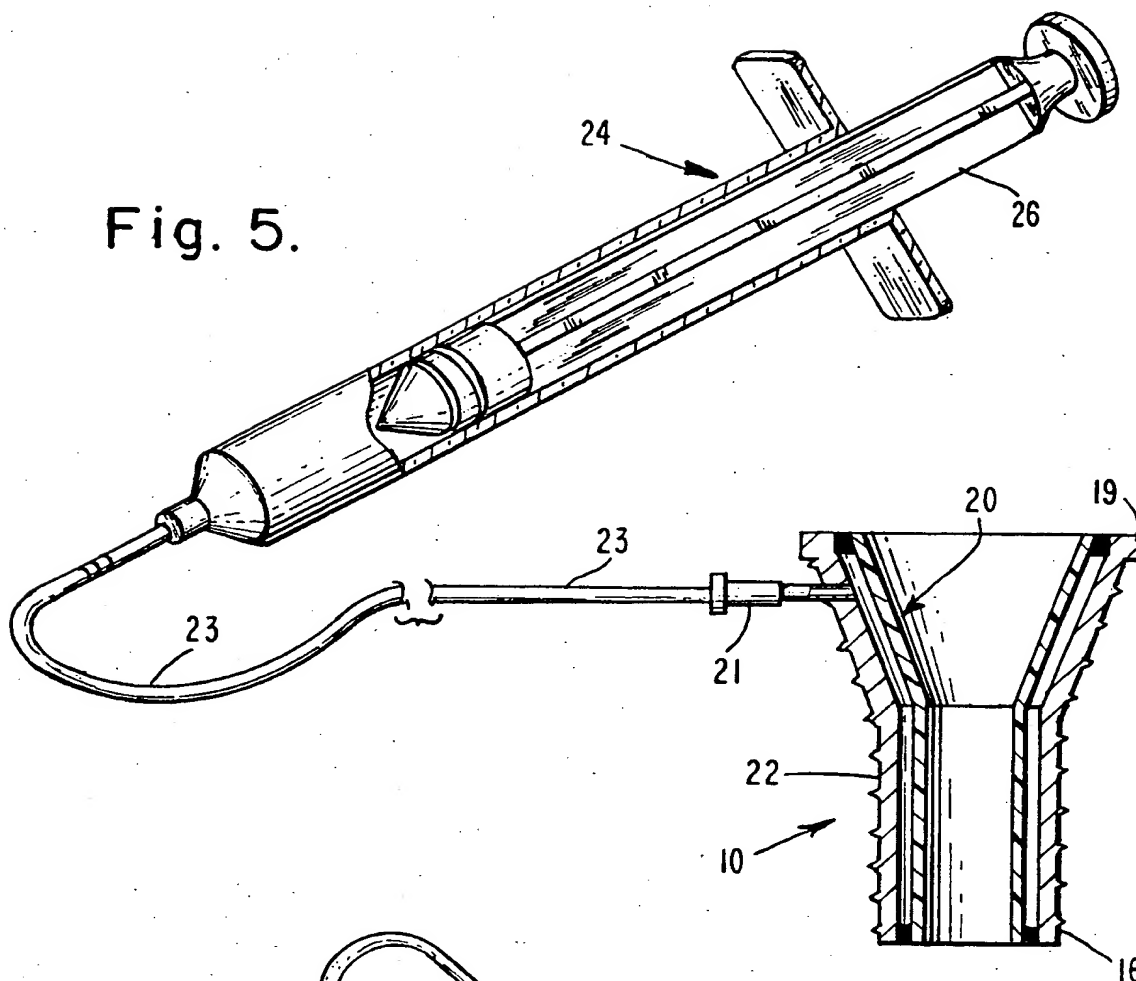
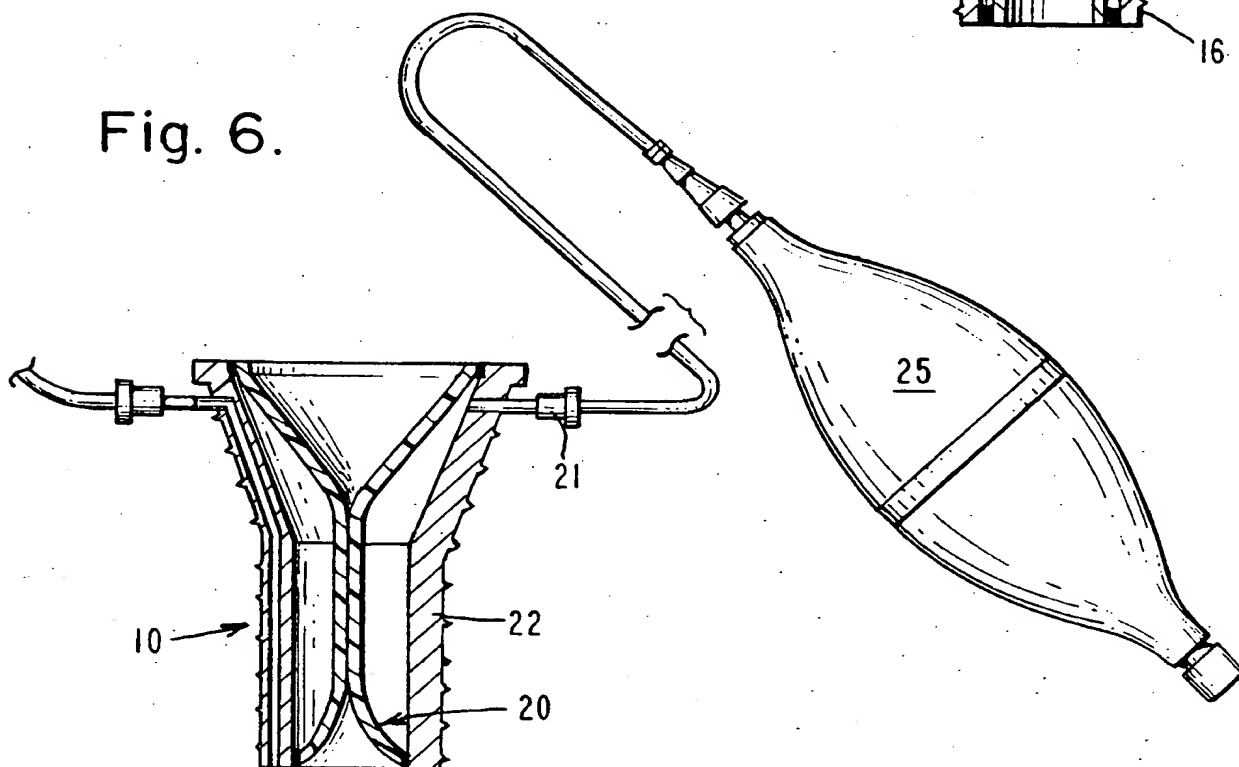


Fig. 6.

**SUBSTITUTE SHEET (RULE 26)**

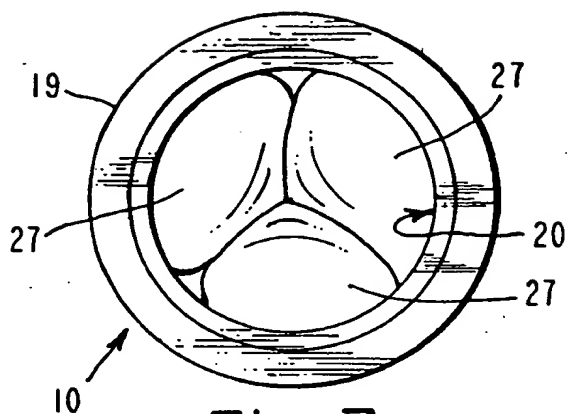


Fig. 7.

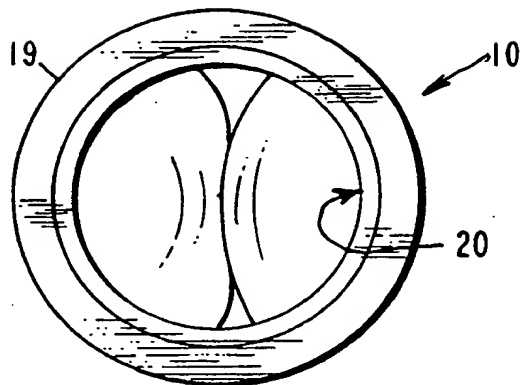


Fig. 7a.

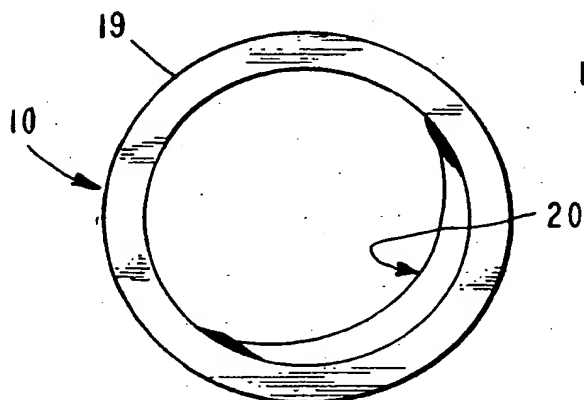


Fig. 7b.

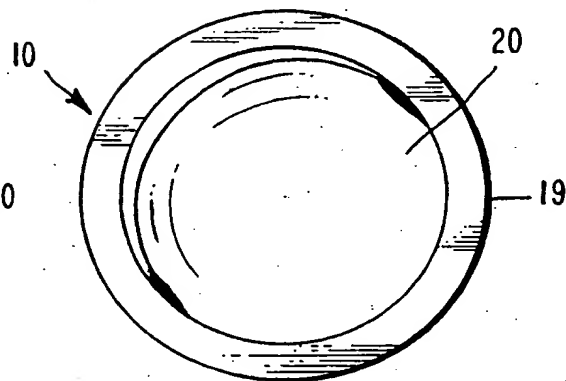


Fig. 7c.

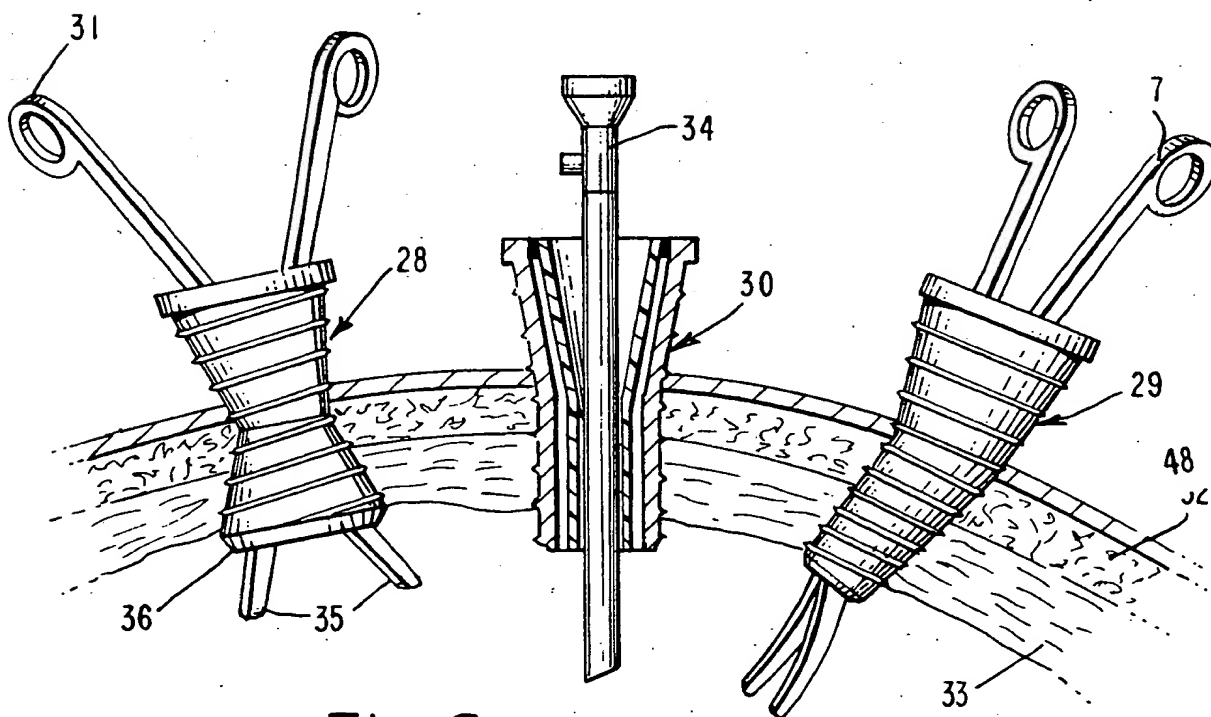


Fig. 8.

SUBSTITUTE SHEET (RULE 26)

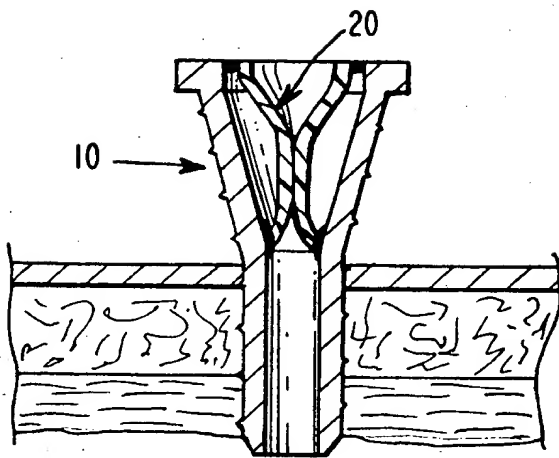


Fig. 6a.

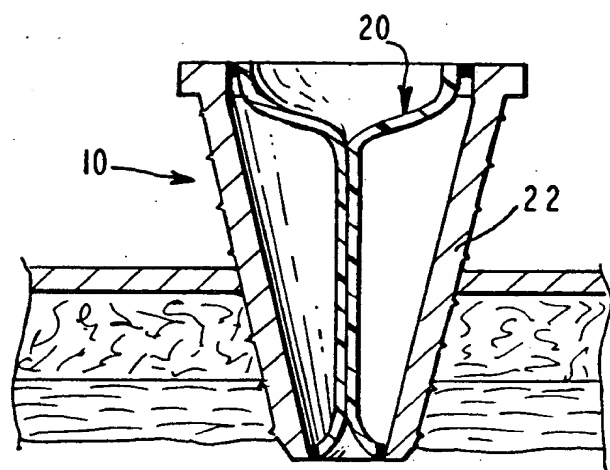


Fig. 6b.

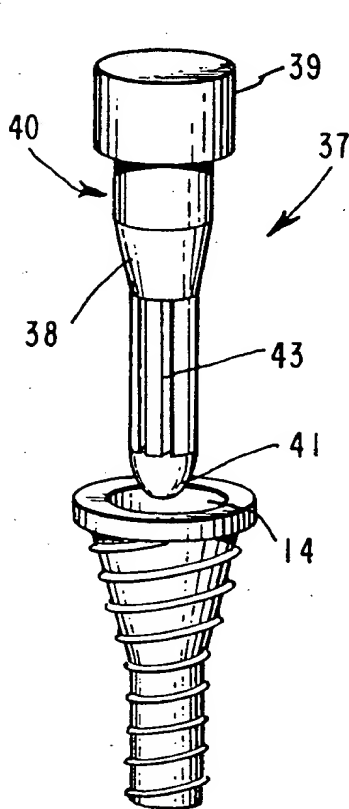


Fig. 9.

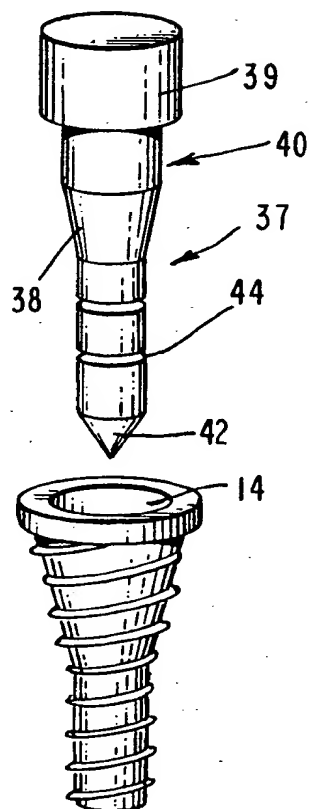


Fig. 10

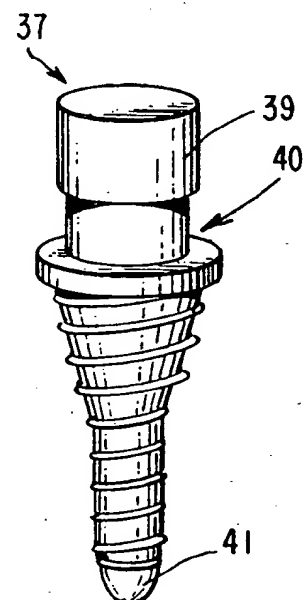


Fig. 11.

SUBSTITUTE SHEET (RULE 26)

Fig. 12.

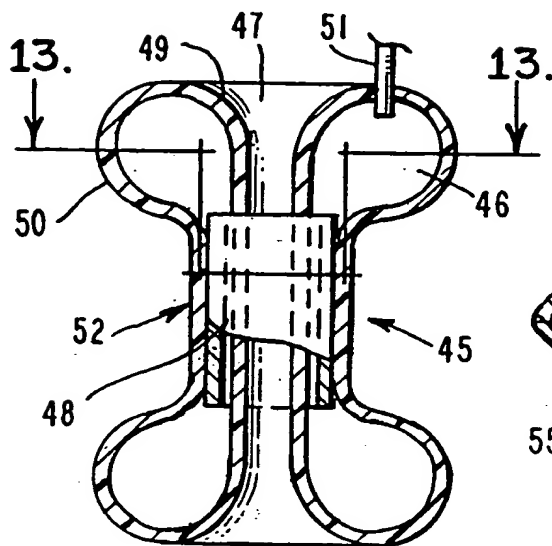


Fig. 13.

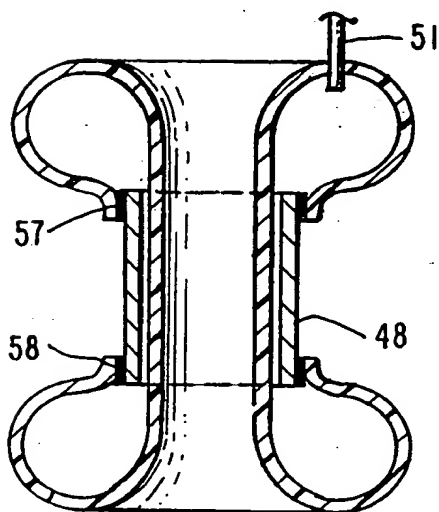
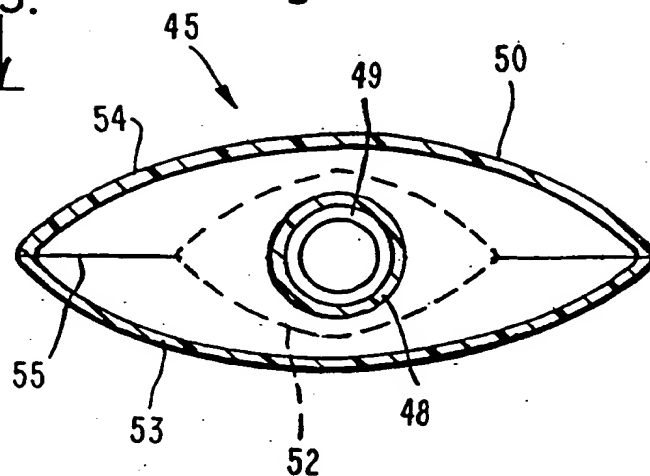
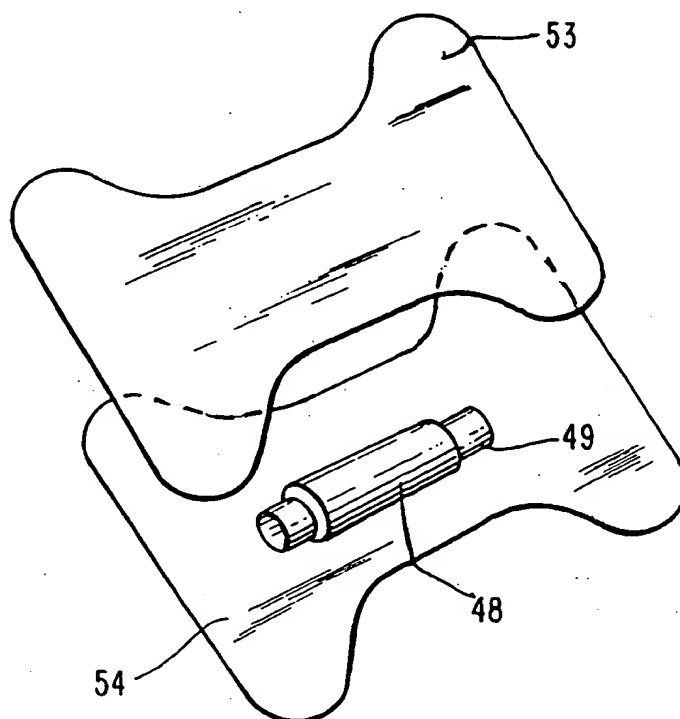


Fig. 14.

Fig. 15.

**SUBSTITUTE SHEET (RULE 26)**

8 / 8

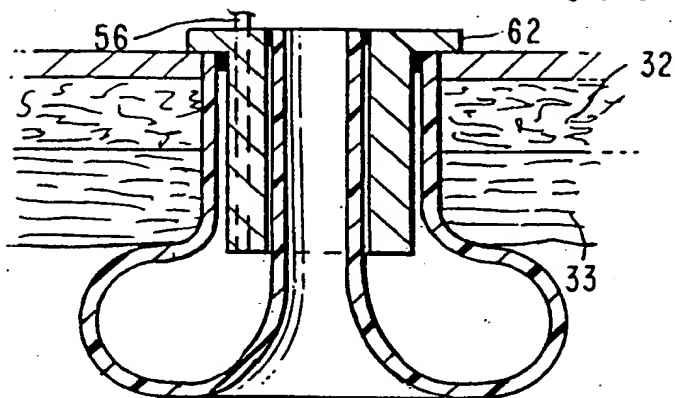


Fig. 18.

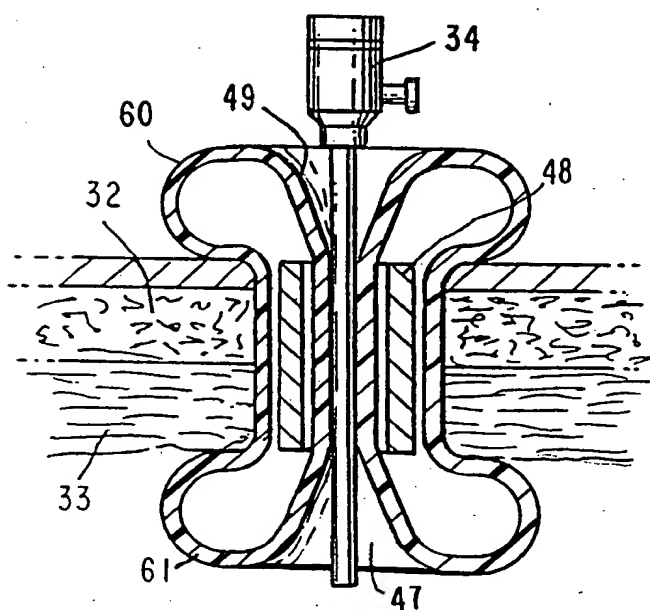


Fig. 17.

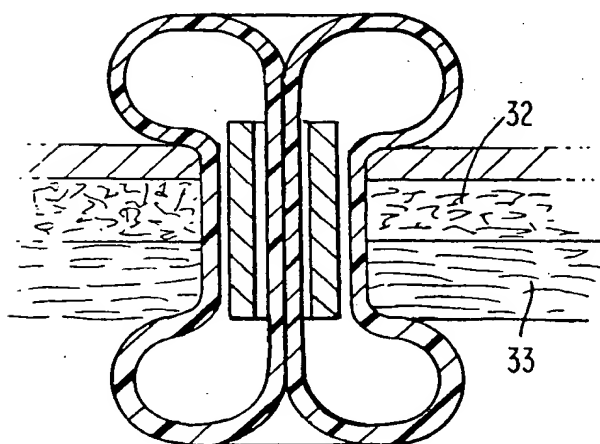


Fig. 17b.

Fig. 16.

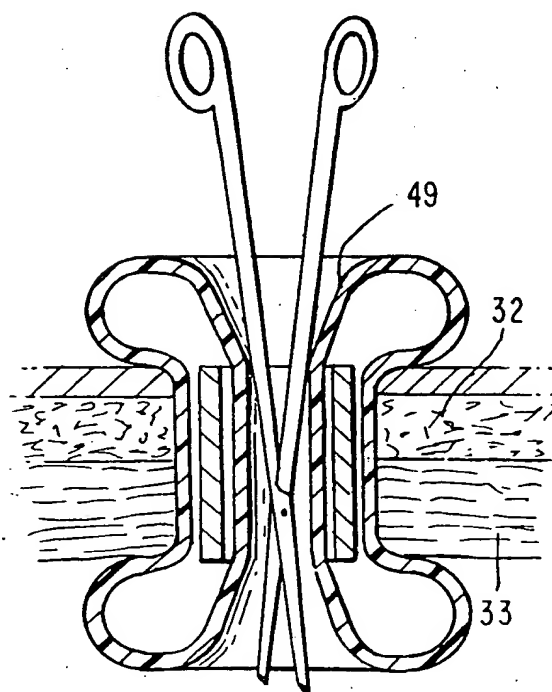
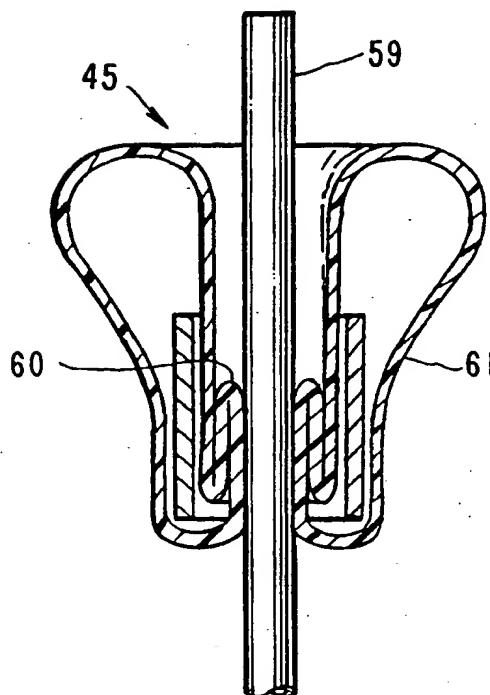


Fig. 17a.

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/07220**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 17/00

US CL :606/213

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/213, 215, 216

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5,413,571 (KATSAROS ET AL.) 09 MAY 1995, see Figs. 7 and 8.	2-4, 6, 7
X --- Y	US, A, 4,555,242 (SAUDAGAR) 26 November 1985, see Fig. 1.	8-13
A	US, A, 5,366,478 (BRINKERHOFF ET AL.) 22 November 1994, see entire document.	1-13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

17 JULY 1996

Date of mailing of the international search report

14 AUG 1996

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3590

Authorized officer

MARK S. LEONARDO

Telephone No. (703) 308-1320

